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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/574,903

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EXAMINER

SCHNIZER, RICHARD A

ART UNIT

PAPER NUMBER

1635

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/574,903	Applicant(s) BROWN ET AL.	
	Examiner Richard Schnizer, Ph. D.	Art Unit 1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-22 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claim Objections

Claims 16-22 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from another multiple dependent claim. See MPEP § 608.01(n). Accordingly, claims 16-22 have not been further treated on the merits.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claim(s) 1-10 and 15, drawn to a compound that specifically targets a nucleic acid molecule encoding SEQ ID NO: 24 or a sequence encoding one or more conservative amino acid substitutions of SEQ ID NO 24.

Group 2, claim(s) 1-10 and 15, drawn to a compound that specifically targets a nucleic acid molecule encoding SEQ ID NO: 25 or a sequence encoding one or more conservative amino acid substitutions of SEQ ID NO 25.

Group 3 claim(s) 1-10 and 15, drawn to a compound that specifically targets a nucleic acid molecule encoding SEQ ID NO: 26 or a sequence encoding one or more conservative amino acid substitutions of SEQ ID NO 26.

Group 4, claims 11-13, drawn to an antibody that specifically targets SEQ ID NO: 24 or a hyaluronan synthase sequence containing one or more conservative amino acid substitutions of SEQ ID NO: 24.

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Group 5, claims 11-13, drawn to an antibody that specifically targets SEQ ID NO: 25 or a hyaluronan synthase sequence containing one or more conservative amino acid substitutions of SEQ ID NO: 25.

Group 6, claims 11-13, drawn to an antibody that specifically targets SEQ ID NO: 26 or a hyaluronan synthase sequence containing one or more conservative amino acid substitutions of SEQ ID NO: 26.

Group 7, claim 14, drawn to a small molecule that specifically targets SEQ ID NO: 24 or a hyaluronan synthase sequence containing one or more conservative amino acid substitutions of SEQ ID NO: 24.

Group 8, claims 14, drawn to a small molecule that specifically targets SEQ ID NO: 25 or a hyaluronan synthase sequence containing one or more conservative amino acid substitutions of SEQ ID NO: 25.

Group 9, claims 14, drawn to a small molecule that specifically targets SEQ ID NO: 26 or a hyaluronan synthase sequence containing one or more conservative amino acid substitutions of SEQ ID NO: 26.

Claims 1, 2, and 15, to the extent that they are drawn to a compound that specifically targets SEQ ID NO: 24, link inventions 4 and 7. Claims 1, 2, and 15, to the extent that they are drawn to a compound that specifically targets SEQ ID NO: 25, link inventions 5 and 8. Claims 1, 2, and 15, to the extent that they are drawn to a compound that specifically targets SEQ ID NO: 26, link inventions 6 and 9.

The restriction requirement between linked inventions is subject to the nonallowance of the claim(s) linking the inventions. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Claims 1-10 and 15, to the extent that they are drawn to compounds that are nucleic acids, are generic to groups 1-3. Claims 11-13 are generic to groups 4-6. Claim 14 is generic to groups 7-9. The generic claims in the elected group will be examined to the extent that they are defined by that group. Linking claims will be examined to the extent necessary to show that they are unpatentable, or the restriction requirement between linked inventions will be withdrawn upon allowance.

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The inventions listed as Groups 1-9 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Groups 1-3 are drawn to nucleic acids that target nucleic acid sequences. Groups 4-6 are drawn to antibodies that target amino acid sequences. Groups 7-9 to small molecules that target amino acid sequences.

According to the guidelines in Section (f)(i) of Annex B of the PCT Administrative Instructions, the special technical feature as defined by PCT Rule 13.2 shall be considered to be met when all the alternatives of a Markush-group are of similar nature. For chemical alternatives, such as the claimed antisense sequences, the Markush group shall be regarded as being of similar nature when

(A) all alternatives have a common property or activity, and

(B)(1) a common structure is present, i.e., a significant structural element is shared by all of the alternatives, or

(B)(2) in cases where the common structure cannot be the unifying criteria, all alternatives belong to a recognized class of chemical compounds in the art to which the invention pertains.

Groups 1-3 lack a corresponding technical feature with groups 4-9 because nucleic acids are a completely different class of molecules than antibodies or small molecules. They have no common property or activity with antibodies or small molecules, and have no common structure with antibodies or small molecules. Accordingly there is no unity of invention between groups 1-3 and groups 4-9.

Similarly, the antibodies of groups 4-6 have no common structure in common with the small molecules of groups 7-9, and therefore share no special technical feature and lack unity of invention therewith.

The nucleic acids of groups 1-3 lack unity of invention with each other because, although the claimed nucleic acids may target the same gene, each sequence behaves in a different way in the context of the claimed invention. Each sequence targets a different and specific region of the gene. Further, although the sequences may target the same gene, the sequences do not meet the criteria of (B)(1), as they do not share, one with another, a common core structure. Accordingly, unity of invention between the claimed nucleic acid sequences is lacking and each nucleic acid sequence claimed is considered to constitute a special technical feature. Similar reasoning applies to the antibodies of groups 4-6, and the small molecules of groups 7-9. Each antibody is targeted to a different site with a different structure, therefore the portion of each antibody that is critical to the invention, i.e. the binding region, is structurally and functionally distinct in each case. Therefore the antibodies fail to meet criteria (B)(1). The same applies to the small molecules of groups 7-9.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Richard Schnizer, whose telephone number is 571-272-0762. The examiner can normally be reached Monday through Friday between the hours of 6:00 AM and 3:30. The examiner is off on alternate Fridays, but is sometimes in the office anyway.

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, J. Douglas Schultz, can be reached at (571) 272-0763. The official central fax number is 571-273-8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system

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provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

/Richard Schnizer, Ph. D./
Primary Examiner, Art Unit 1635